

### **REMARKS**

In response to the Office Action of October 7, 2009, Applicants hereby submit the following remarks. Claims 1-43, 46 and 49-55 are currently pending. Claims 1-42 have been cancelled. Claims 43, 49 and 51 have been amended. Claims 43, 46 and 49-55 have been rejected. Applicants thank the Examiner for withdrawing the rejections to 103(a). In light of the remarks below, reconsideration and allowance are respectfully requested.

#### *The Claims*

The claims are drawn to a vector for expressing GAD65 in cells of the central nervous system comprising an AAV vector, tissue specific promoter and a WPRE post-transcriptional regulatory element. Claim 43 has been amended to further clarify the woodchuck post-transcriptional regulatory element. Support for the amendment can be found throughout the specification and, for example, in paragraph [0149] of the published application. Claim 49 has been amended to define the term “CBA” as cytomegalovirus enhancer/chicken-actin. Support for the amendment can be found in paragraph [0074] of the published application. Claim 51 has been amended to recite “the vector is *formulated in a pharmaceutical composition for in vivo administration* capable of transducing cells of the central nervous system (CNS).” Support for the amendment can be found in paragraphs [0136] and [0140] of the published specification.

#### *Objections*

Claim 49 is objected to for the recitation of “CBA” and no accompanying definition. Amended claim 49 recites “wherein the promoter is a cytomegalovirus enhancer/chicken-actin (CBA) promoter.” In light of the amendments, Applicants respectfully request reconsideration.

The Examiner also objects to claim 51 as failing to further limit the subject matter of a previous claim. Amended claim 51 is directed to the vector formulated in a pharmaceutical composition for in vivo administration capable of transducing cells of the CNS and limits the subject matter of claim 43. Therefore amended claim 51 is compliant with 37 CFR 1.75(c).

*Rejection under 35 U.S.C. §112*

Claims 43, 46 and 49-55 stand rejected under 35 U.S.C. §112 as failing to comply with the written description requirement by 1) failing to demonstrate possession of the invention and 2) failing to enable the full scope of the claims. The claims recite “a woodchuck post-transcriptional regulatory element.” The Examiner contends that although the application recites the use of woodchuck hepadnavirus post-transcriptional regulatory elements, the claims “encompass a genus of genetic elements that are not described.” According to the Examiner, the claims “cover the use of a genus of genetic elements, while providing a description of only a single post-transcriptional regulatory element.” Applicants respectfully disagree.

However, for purposes of advancing prosecution, claim 43 has been amended to recite “a post-transcriptional regulatory element, wherein the post-transcriptional regulatory element is the woodchuck *hepatitis* post-transcriptional regulatory element.” Applicants submit they are in possession of the invention as claimed and have enabled the invention for the entire scope of the claims in light of the amendment to independent claim 43 and the teachings present in the specification. Reconsideration and allowance of claims 43, 46 and 49-55 is respectfully requested.

**CONCLUSION**

Applicants believe that the presently pending claims are in immediate condition for allowance and allowance is therefore respectfully requested. However, should any issues remain, the Examiner is urged to telephone the undersigned Attorney for Applicant in the event that such a communication is deemed to expedite allowance of this application.

Applicants believe that no fee is required. However, if any additional fee is due, the Commissioner is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 141449, under Order No. 102182-36.

Dated: December 7, 2009

Respectfully submitted,

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